

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	) ) ) ) _____)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	) )	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. August 30, 2007

Pamela A. Pecora ("Ms. Pecora" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In November 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Mayank K. Parikh, M.D. Based on an echocardiogram dated October 8, 2002, Dr. Parikh attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.<sup>3</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$528,405.

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2(...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Parikh also attested that Ms. Pecora had mild aortic regurgitation. As Ms. Pecora's claim does not present any of the conditions necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2) (a).

In the report of claimant's echocardiogram, Dr. Parikh stated that claimant had moderate mitral regurgitation, which he measured as 25%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Parikh also stated that claimant had an abnormal left atrial dimension, which he measured as 5.4 cm in the apical four chamber view. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b).

In October 2003, the Trust forwarded the claim for review by Yelena German, M.D., one of its auditing cardiologists. In audit, Dr. German concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. German concluded that "[o]nly mild MR was appretiated [sic]. MR jet area of 4.34cm was overestimated. Two other areas of 5.03 and 5.56cm were grossly overestimated." Dr. German, however, found

that there was a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension.<sup>4</sup>

Based on Dr. German's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Pecora's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>5</sup> Claimant submitted an expert report by Naim M. Al-Adli, M.D., F.A.C.C., in which he confirmed the attesting physician's finding of moderate mitral regurgitation. He further stated that "Dr. Yelena German's claim that mitral regurgitation is mild is completely incorrect. It is obvious that [s]he did not review the Echocardiogram on 8/9/02. Mitral Regurgitation is moderate, RJA/LAA = 0.25."

Based on claimant's contest, the Trust submitted the claim to Dr. German for a second review. Dr. German reaffirmed her

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the conditions needed to qualify for Level II benefits, the only issue is claimant's level of mitral regurgitation.

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Pecora's claim.

initial finding of mild mitral regurgitation. In particular, Dr. German stated:

In connection with my review, I evaluated Claimant's mitral regurgitant jet area ("RJA") and left atrial area ("LAA") in the frame relied upon by Claimant's Attesting and Reviewing Physicians. I found that Claimant's Attesting and Reviewing Physicians improperly inflated Claimant's level of mitral regurgitation by relying upon an RJA that was overtraced to include black pixels and low velocity flow. I properly measured Claimant's RJA and LAA and again determined that Claimant has mild mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Pecora's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Pecora's claim should be paid. On February 9, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4470 (Feb. 9, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 7, 2005. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor<sup>6</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, claimant submitted an expert report by Allen L. Dollar, M.D., F.A.C.C.<sup>7</sup> In the report, Dr. Dollar stated:

The MR is best demonstrated and measured in video frame 000284. The MR jet is planimetered at 4.34cm<sup>2</sup> in that frame. The Nyquist limit is set at a reasonable 65 cm/s. The jet is a pan-systolic dense mosaic jet that reaches from the mitral valve all the way to the posterior wall of the left atrium. The tracing excludes the rim of dark blue low-velocity blood flow and is a very reasonable and honest representation of the size of the MR jet. The LA area is measured in video frame 00654 at 20.0 cm<sup>2</sup>. This calculates to a MR/LAA ratio of 21.7%.

From my review of the tape, the MR jet is quite clear and measured honestly. The jet is obvious, lasts throughout systole, is seen in both the apical 2 and 4-chamber views, and reaches all the way to the back of the LA. By our usual clinical criteria of visual appearance, this is Moderate MR and by the Settlement Trust MR ratio criteria this is also Moderate MR.

Claimant argues that the findings of Drs. Parikh, Al-Adli, and Dollar provide a reasonable medical basis for her claim. She further contends that the "Trust has relied only on the mere difference of Dr. German's opinion rather than any factual measurements in denying [her] Matrix claim." Finally, claimant asserts that Dr. German's "general assessment" does not allow her "to assess the validity or the accuracy of the measurements" upon which Dr. German relied.

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7. Claimant also resubmitted Dr. Al-Adli's expert report.

In response, the Trust argues that claimant's physicians relied upon inaccurate tracings in reaching their finding that claimant had moderate mitral regurgitation. The Trust further asserts that claimant's expert, Dr. Dollar, improperly based his finding on a single frame rather than on multiple loops of the echocardiogram. Finally, the Trust contends that the auditing cardiologist complied with the Settlement Agreement in the manner in which she reviewed claimant's echocardiogram.<sup>8</sup>

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson concluded that:

In reviewing the transthoracic echocardiogram, my visual estimate is that there is mild to moderate mitral regurgitation, which could reasonably be read as moderate. To confirm my visual evaluation, I measured the mitral regurgitant jet and the left atrial area in the same frame in five representative cardiac cycles. Based on these measurements, I calculated RJA/LAA ratios which were slightly less than or equal to 20%, which confirmed my visual estimate.

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8. In its show cause submissions, the Trust also argues that, under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 (Feb. 26, 2007).



In summary, I believe the mitral regurgitation in this Claimant is mild to moderate, and it would be possible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate. There is a reasonable medical basis for the Attesting Physician's claim that Pamela Pecora has moderate mitral regurgitation.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Parikh, reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation.<sup>9</sup> Although the Trust contested the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's finding.<sup>10</sup> Specifically, Dr. Abramson concluded that claimant's "RJA/LAA ratios ... were slightly less than or equal to 20%."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Abramson measured five representative cardiac cycles and determined that claimant's level of mitral regurgitation was slightly less than or equal to 20%. As claimant's RJA/LAA ratio has been read as equal to 20%,

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9. Although unnecessary for resolution of this claim, as noted above, claimant also submitted expert reports of two additional cardiologists who similarly concluded that claimant had moderate mitral regurgitation.

10. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Rule 34.

claimant's level of mitral regurgitation meets the Settlement Agreement criteria for moderate mitral regurgitation. Therefore, under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.<sup>11</sup>

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix Benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Pecora.

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11. Accordingly, we need not address claimant's remaining arguments.

